

Serial Number: 09/754,775

Filing Date: January 4, 2001

Title: PREVENTION AND TREATMENT OF CARDIOVASCULAR PATHOLOGIES WITH TAMOXIFEN ANALOGUES

Remarks

Reconsideration and withdrawal of the rejections of the claims in view of the remarks presented herein is respectfully requested. Claims 173-194, 196-203, 205-211, and 231 are pending.

The Examiner is respectfully thanked for the voice mail message left for Applicant's Representatives on August 19, 2003, which clarified that claims 1-2 of U.S. Patent No. 6,197,789 were rejected under the judicially-created doctrine of obviousness-type double patenting.

The Examiner rejected claims 173-194, 196-203, 205-211, and 231 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,197,789, claim 8 of U.S. Patent No. 6,117,911, claims 1-7 of U.S. Patent No. 5,595,722, and claims 36-38 of U.S. Patent No. 5,770,609. A terminal disclaimer over U.S. Patent Nos. 5,770,609 and 6,197,789 is enclosed herewith, thereby obviating the double-patenting rejection over the '609 and '789 patents. The obvious-type double patenting rejection over the '911 and '722 patents is respectfully traversed.

A double patenting rejection of the obviousness type is 'analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. 103 except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 U.S.P.Q. 29 (C.C.P.A. 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness determination." M.P.E.P. § 804, emphasis added. A double patenting rejection must rely on a comparison with the claims in an issued patent [not the complete disclosure of the issued patent]. M.P.E.P. § 804.III, emphasis added.

Claims 173-181, 196-199, and 206-211 of the present application are directed to therapeutic methods for preventing or treating a cardiovascular indication or vascular indication characterized by a decreased lumen diameter involving administering a compound of formula (I), i.e., a compound which is structurally related to tamoxifen.

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Claims 182-194, 196-199, and 205-206 of the present application are directed to therapeutic methods of increasing the level of TGF-beta in a mammal involving administering a compound of formula (I), a compound which is structurally related to tamoxifen.

Claims 200-203 and 205-206 of the present application are directed to a method of increasing the level of TGF-beta in a mammal in need thereof, involving administering an effective amount of an agent that directly or indirectly elevates the level of active TGF-beta in the mammal, wherein the agent has reduced estrogenic activity relative to tamoxifen, reduced DNA adduct formation relative to tamoxifen, or any combination thereof.

Claim 231 of the present application is directed to a therapeutic method for treating a condition selected from the group consisting of arteriosclerosis and small vessel disease, involving administering to a mammal afflicted with the condition, an effective amount of a compound of formula I, a compound which is structurally related to tamoxifen.

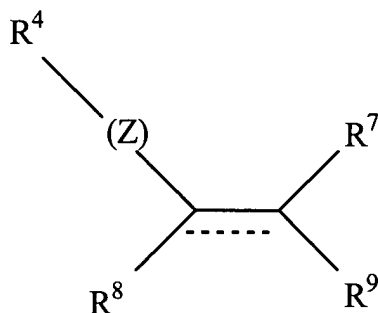
Claim 8 of the '911 patent is directed to a therapeutic method for lowering serum cholesterol comprising administering to a mammal in need of such therapy, an effective amount of a compound of formula VI:

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(VI)



Claim 8 of the '911 patent does not disclose or suggest the use of a compound of formula (I), e.g., to prevent or treat a cardiovascular indication or vascular indication characterized by a decreased lumen diameter, to increase the level of TGF-beta in a mammal or to treat arteriosclerosis or small vessel disease.

Claims 1-7 of U.S. Patent No. 5,595,722 are directed to a method for identifying an agent which increases the level of TGF-beta in a human.

Claims 1-7 of the '722 patent do not disclose or suggest the use of a compound of formula (I). Nor do they disclose or suggest that a compound of formula (I) would increase the level of TGF-beta, or is useful to prevent or treat a cardiovascular or vascular indication characterized by a decreased lumen diameter.

Accordingly, withdrawal of the non-statutory obviousness-type double patenting rejections is respectfully requested.

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Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

DAVID J. GRAINGER ET AL.,

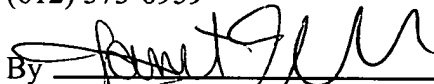
By their Representatives,

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Date

December 5, 2003

By



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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 5th day of December, 2003.

Name

Dawn M. Poole

Signature

Dawn M. Poole